IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re Sitagliptin Phosphate ('708 & '921) Patent Litigation	C.A. No. 19-md-2902-RGA
MERCK SHARP & DOHME CORP., *Plaintiff,* v. MACLEODS PHARMACEUTICALS LIMITED, and MACLEODS PHARMA USA, INC., *Defendants*.	C.A. No. 19-cv-00316-RGA

FIRST AMENDED COMPLAINT

Plaintiff Merck Sharp & Dohme Corp. ("Merck"), by its attorneys, for its First Amended Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of defendants' submission of Abbreviated New Drug Application ("ANDA") Nos. 211073 and 212338 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import versions of JANUVIA® (sitagliptin phosphate) and JANUMET® (metformin hydrochloride; sitagliptin phosphate) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent") and U.S. Patent No. 8,414,921 ("the '921 patent").

2. Macleods Pharmaceuticals Limited notified Merck by letter dated November 20, 2018 ("Macleods's '073 Notice Letter") that it had submitted to the FDA ANDA No. 211073 ("Macleods's '073 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic sitagliptin phosphate oral tablets ("Macleods's '073 ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Macleods's '073 ANDA Product is a generic version of Merck's JANUVIA®.

4. Macleods Pharmaceuticals Limited and Macleods Pharma USA, Inc. notified Merck by letter dated November 20, 2018 ("Macleods's '338 Notice Letter") that it had submitted to the FDA ANDA No. 212338 ("Macleods's '338 ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic metformin hydrochloride and sitagliptin phosphate oral tablets ("Macleods's '338 ANDA Product") prior to the expiration of the '708 patent and the '921 patent.

5. On information and belief, Macleods's '338 ANDA Product is a generic version of Merck's JANUMET®.

6. Macleods's '073 Notice Letter and Macleods's '338 Notice Letter are collectively referred to herein as "Macleods's Notice Letters." Macleods's '073 ANDA and Macleods's '338 ANDA are collectively referred to herein as "Macleods's ANDAs." Macleods's '073 ANDA Product and Macleods's '338 ANDA Product are collectively referred to herein as "Macleods's ANDA Products."

PARTIES

7. Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

8. Merck is the holder of New Drug Application ("NDA") No. 21995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

9. Merck is the holder of NDA No. 22044 for JANUMET® (metformin hydrochloride; sitagliptin phosphate), which has been approved by the FDA.

10. On information and belief, defendant Macleods Pharmaceuticals Limited ("Macleods Limited") is a corporation organized and existing under the laws of India, having its corporate offices and principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India. On information and belief, Macleods Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Macleods Pharma USA, Inc.

11. On information and belief, defendant Macleods Pharma USA, Inc. ("Macleods Pharma") is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, NJ, 08536. On information and belief, Macleods Pharma is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

12. On information and belief, Macleods Pharma is a wholly owned subsidiary of Macleods Limited. Macleods Limited and Macleods Pharma are collectively referred to herein as "Macleods."

13. On information and belief, Macleods Limited and Macleods Pharma acted in concert to prepare and submit Macleods's ANDAs to the FDA.

14. On information and belief, Macleods Limited and Macleods Pharma know and intend that upon approval of Macleods's ANDAs, Macleods will manufacture, market, sell, and distribute Macleods's ANDA Products throughout the United States, including in Delaware. On information and belief, Macleods Limited and Macleods Pharma are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Macleods's ANDA Products, and enter into agreements that are nearer than arm's length. On information and belief, Macleods Limited and Macleods Pharma participated, assisted, and cooperated in carrying out the acts complained of herein.

15. On information and belief, following any FDA approval of Macleods's ANDAs, Macleods Limited and Macleods Pharma will act in concert to distribute and sell Macleods's ANDA Products throughout the United States, including within Delaware.

JURISDICTION

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Macleods.

18. Macleods Limited is subject to personal jurisdiction in Delaware because, among other things, Macleods Limited, itself and through its wholly owned subsidiary Macleods Pharma, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Macleods Limited, itself and through its wholly owned subsidiary Macleods Pharma, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of

Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Macleods Limited is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Macleods Pharma and therefore the activities of Macleods Pharma in this jurisdiction are attributed to Macleods Limited.

19. Macleods Pharma is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Macleods Pharma is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Macleods Pharma develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

20. In addition, this Court has personal jurisdiction over Macleods because Macleods Limited and Macleods Pharma regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *H. Lundbeck A/S v. Macleods Pharms. Ltd.*, No. 18-91, D.I. 13 (D. Del. Mar. 30, 2018); *Biogen Int'l GmbH v. Macleods Pharms. Ltd.*, No. 17-857, D.I. 7 (D. Del. July 17, 2017); *Amgen, Inc. v. Macleods Pharms. Ltd.*, No. 17-817-GMS, D.I. 9 (D. Del. July 17, 2017); *Bristol-Myers Squibb Co. v. Macleods Pharms. Ltd.*, No. 17-405-

LPS, D.I. 8 (D. Del. June 28, 2017); *Bayer Pharma AG v. Macleods Pharms. Ltd.*, No. 15-464-GMS, D.I. 14 (D. Del. Aug. 31, 2015).

21. On information and belief, if Macleods's ANDAs are approved, Macleods will manufacture, market, sell, and/or distribute Macleods's ANDA Products within the United States, including in Delaware, consistent with Macleods's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Macleods regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Macleods's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Macleods's ANDA Products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Merck's patent in the event that Macleods's ANDA Products are approved before the patent expires.

22. On information and belief, Macleods derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Macleods and/or for which Macleods Limited and/or Macleods Pharma is/are the named applicant(s) on approved ANDAs. On information and belief, various products for which Macleods Limited and/or Macleods Pharma is/are the named applicant(s) on approved ANDAs are available at retail pharmacies in Delaware.

VENUE

23. Merck incorporates each of the preceding paragraphs 1–22 as if fully set forth herein.

24. Venue is proper in this district as to Macleods Limited under 28 U.S.C. § 1391 because Macleods Limited is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

25. Venue is proper in this district as to Macleods Pharma under 28 U.S.C. § 1400(b) because Macleods Pharma is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

THE '708 PATENT

26. Merck incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

27. The inventors named on the '708 patent are Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr.

28. The '708 patent, entitled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor" (attached as Exhibit A), was duly and legally issued on February 5, 2008.

29. Merck is the owner and assignee of the '708 patent.

30. The '708 patent claims, *inter alia*, a dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I, or a hydrate thereof, as recited in claim 1 of the '708 patent.

31. JANUVIA®, as well as methods of using JANUVIA®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUVIA® in the FDA's Orange Book.

32. JANUMET®, as well as methods of using JANUMET®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUMET® in the FDA's Orange Book.

THE ’921 PATENT

33. Merck incorporates each of the preceding paragraphs 1–32 as if fully set forth herein.

34. The inventors named on the ’921 patent are Ashkan Kamali, Laman Alani, Kyle A. Fliszar, Soumojeet Ghosh, and Monica Tijerina.

35. The ’921 patent, entitled “Pharmaceutical Compositions of Combinations of Dipeptidyl Peptidase-4 Inhibitors with Metformin” (attached as Exhibit B), was duly and legally issued on April 9, 2013.

36. Merck is the owner and assignee of the ’921 patent.

37. The ’921 patent claims, *inter alia*, a pharmaceutical composition comprising: (a) about 3 to 20% by weight of sitagliptin, or a pharmaceutically acceptable salt thereof; (b) about 25 to 94% by weight of metformin hydrochloride; (c) about 0.1 to 10% by weight of a lubricant; (d) about 0 to 35% by weight of a binding agent; (e) about 0.5 to 1% by weight of a surfactant; and (f) about 5 to 15% by weight of a diluent, as recited in claim 1 of the ’921 patent.

38. JANUMET®, as well as methods of using JANUMET®, are covered by one or more claims of the ’921 patent, including claim 1 of the ’921 patent, and the ’921 patent has been listed in connection with JANUMET® in the FDA’s Orange Book.

COUNT I – INFRINGEMENT OF THE ’708 PATENT (MACLEODS’S ’073 ANDA PRODUCT)

39. Merck incorporates each of the preceding paragraphs 1–38 as if fully set forth herein.

40. In Macleods’s ’073 Notice Letter, Macleods notified Merck of the submission of Macleods’s ’073 ANDA to the FDA. The purpose of this submission was to obtain approval

under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Macleods's '073 ANDA Product prior to the expiration of the '708 patent.

41. In Macleods's '073 Notice Letter, Macleods also notified Merck that, as part of its ANDA, Macleods had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Macleods submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Macleods's '073 ANDA Product.

42. In Macleods's '073 Notice Letter, Macleods stated that Macleods's '073 ANDA Product contains sitagliptin phosphate as an active ingredient.

43. Macleods's '073 ANDA Product, and the use of Macleods's '073 ANDA Product, are covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Macleods's '073 ANDA Product.

44. In Macleods's '073 Notice Letter, Macleods did not contest infringement of claim 1 of the '708 patent.

45. Macleods's submission of Macleods's '073 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's '073 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

46. On information and belief, Macleods will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's '073 ANDA Product immediately and imminently upon approval of its ANDA.

47. The manufacture, use, sale, offer for sale, or importation of Macleods's '073 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

48. On information and belief, the manufacture, use, sale, offer for sale, or importation of Macleods's '073 ANDA Product in accordance with, and as directed by its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

49. On information and belief, Macleods plans and intends to, and will, actively induce infringement of the '708 patent when Macleods's '073 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Macleods's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

50. On information and belief, Macleods knows that Macleods's '073 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Macleods's '073 ANDA Product is not a staple article or commodity of commerce, and that Macleods's '073 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Macleods plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Macleods's '073 ANDA.

51. Notwithstanding Macleods's knowledge of the claims of the '708 patent, Macleods has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or

import Macleods's '073 ANDA Product with its product labeling following FDA approval of Macleods's '073 ANDA prior to the expiration of the '708 patent.

52. The foregoing actions by Macleods constitute and/or will constitute infringement of the '708 patent; active inducement of infringement of the '708 patent; and contribution to the infringement by others of the '708 patent.

53. On information and belief, Macleods has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringement of the '708 patent; active inducement of infringement of the '708 patent; and/or contribution to the infringement by others of the '708 patent.

54. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

55. Unless Macleods is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT (MACLEODS'S '073 ANDA PRODUCT)

56. Merck incorporates each of the preceding paragraphs 1–55 as if fully set forth herein.

57. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Macleods on the other regarding Macleods's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

58. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Macleods's '073 ANDA Product with its proposed labeling, or any other

Macleods drug product that is covered by or whose use is covered by the ’708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’708 patent, and that the claims of the ’708 patent are valid.

COUNT III – INFRINGEMENT OF THE ’708 PATENT
(MACLEODS’S ’338 ANDA PRODUCT)

59. Merck incorporates each of the preceding paragraphs 1–58 as if fully set forth herein.

60. In Macleods’s ’338 Notice Letter, Macleods notified Merck of the submission of Macleods’s ’338 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Macleods’s ’338 ANDA Product prior to the expiration of the ’708 patent.

61. In Macleods’s ’338 Notice Letter, Macleods also notified Merck that, as part of its ANDA, Macleods had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the ’708 patent. On information and belief, Macleods submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Macleods’s ’338 ANDA Product.

62. In Macleods’s ’338 Notice Letter, Macleods stated that Macleods’s ’338 ANDA Product contains sitagliptin phosphate as an active ingredient.

63. Macleods’s ’338 ANDA Product, and the use of Macleods’s ’338 ANDA Product, are covered by one or more claims of the ’708 patent, including at least claim 1 of the ’708 patent, because claim 1 of the ’708 patent covers the sitagliptin phosphate contained in Macleods’s ’338 ANDA Product.

64. In Macleods's '338 Notice Letter, Macleods did not contest infringement of claim 1 of the '708 patent.

65. Macleods's submission of Macleods's '338 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's '338 ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

66. On information and belief, Macleods will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's '338 ANDA Product immediately and imminently upon approval of its ANDA.

67. The manufacture, use, sale, offer for sale, or importation of Macleods's '338 ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

68. On information and belief, the manufacture, use, sale, offer for sale, or importation of Macleods's '338 ANDA Product in accordance with, and as directed by Macleods's proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

69. On information and belief, Macleods plans and intends to, and will, actively induce infringement of the '708 patent when Macleods's '338 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Macleods's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

70. On information and belief, Macleods knows that Macleods's '338 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Macleods's '338 ANDA Product is not a staple article or commodity of commerce, and that

Macleods's '338 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Macleods plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Macleods's '338 ANDA.

71. Notwithstanding Macleods's knowledge of the claims of the '708 patent, Macleods has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Macleods's '338 ANDA Product with its product labeling following FDA approval of Macleods's '338 ANDA prior to the expiration of the '708 patent.

72. The foregoing actions by Macleods constitute and/or will constitute infringement of the '708 patent; active inducement of infringement of the '708 patent; and contribution to the infringement by others of the '708 patent.

73. On information and belief, Macleods has acted with full knowledge of the '708 patent and without a reasonable basis for believing that it would not be liable for infringement of the '708 patent; active inducement of infringement of the '708 patent; and/or contribution to the infringement by others of the '708 patent.

74. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

75. Unless Macleods is enjoined from infringing the '708 patent, actively inducing infringement of the '708 patent, and contributing to the infringement by others of the '708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '708 PATENT (MACLEODS'S '338 ANDA PRODUCT)

76. Merck incorporates each of the preceding paragraphs 1–75 as if fully set forth herein.

77. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Macleods on the other regarding Macleods's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

78. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Macleods's '338 ANDA Product with its proposed labeling, or any other Macleods drug product that is covered by or whose use is covered by the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '708 patent, and that the claims of the '708 patent are valid.

COUNT V – INFRINGEMENT OF THE '921 PATENT
(MACLEODS'S '338 ANDA PRODUCT)

79. Merck incorporates each of the preceding paragraphs 1–78 as if fully set forth herein.

80. In Macleods's '338 Notice Letter, Macleods notified Merck of the submission of Macleods's '338 ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Macleods's '338 ANDA Product prior to the expiration of the '921 patent.

81. In Macleods's '338 Notice Letter, Macleods also notified Merck that, as part of its ANDA, Macleods had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '921 patent. On information and belief, Macleods submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '921 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Macleods's '338 ANDA Product.

82. Macleods's '338 ANDA Product, and the use of Macleods's '338 ANDA Product, are covered by one or more claims of the '921 patent, including at least claim 1 of the '921 patent, because the composition of Macleods's '338 ANDA Product includes the same or equivalent ingredients as recited in claim 1 of the '921 patent in the same or equivalent amounts.

83. Macleods's submission of Macleods's '338 ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Macleods's '338 ANDA Product before the expiration of the '921 patent was an act of infringement of the '921 patent under 35 U.S.C. § 271(e)(2)(A).

84. On information and belief, Macleods will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Macleods's '338 ANDA Product immediately and imminently upon approval of its ANDA.

85. The manufacture, use, sale, offer for sale, or importation of Macleods's '338 ANDA Product would infringe one or more claims of the '921 patent, including at least claim 1 of the '921 patent.

86. On information and belief, the manufacture, use, sale, offer for sale, or importation of Macleods's '338 ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '921 patent, including at least claim 1 of the '921 patent.

87. On information and belief, Macleods plans and intends to, and will, actively induce infringement of the '921 patent when Macleods's '338 ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Macleods's activities will be done with knowledge of the '921 patent and specific intent to infringe that patent.

88. On information and belief, Macleods knows that Macleods's '338 ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '921 patent, that Macleods's '338 ANDA Product is not a staple article or commodity of commerce, and that Macleods's '338 ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Macleods plans and intends to, and will, contribute to infringement of the '921 patent immediately and imminently upon approval of Macleods's '338 ANDA.

89. Notwithstanding Macleods's knowledge of the claims of the '921 patent, Macleods has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Macleods's '338 ANDA Product with its product labeling following FDA approval of Macleods's '338 ANDA prior to the expiration of the '921 patent.

90. The foregoing actions by Macleods constitute and/or will constitute infringement of the '921 patent; active inducement of infringement of the '921 patent; and contribution to the infringement by others of the '921 patent.

91. On information and belief, Macleods has acted with full knowledge of the '921 patent and without a reasonable basis for believing that it would not be liable for infringement of the '921 patent; active inducement of infringement of the '921 patent; and/or contribution to the infringement by others of the '921 patent.

92. Merck will be substantially and irreparably damaged by infringement of the '921 patent.

93. Unless Macleods is enjoined from infringing the '921 patent, actively inducing infringement of the '921 patent, and contributing to the infringement by others of the '921 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’921 PATENT (MACLEODS’S ’338 ANDA PRODUCT)

94. Merck incorporates each of the preceding paragraphs 1–93 as if fully set forth herein.

95. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Macleods on the other regarding Macleods’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’921 patent.

96. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Macleods’s ’338 ANDA Product with its proposed labeling, or any other Macleods drug product that is covered by or whose use is covered by the ’921 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’921 patent, and that the claims of the ’921 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the ’708 patent has been infringed under 35 U.S.C. § 271(e)(2) by Macleods’s submissions to the FDA of Macleods’s ANDAs;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Macleods’s ANDA Products, or any other drug product that infringes or the use of which infringes the ’708 patent, be not earlier than the latest of the expiration date of the ’708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Macleods, and all persons acting in concert with Macleods, from the commercial manufacture, use, sale, offer for sale, or

importation into the United States of Macleods's ANDA Products, or any other drug product covered by or whose use is covered by the '708 patent, prior to the expiration of the '708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Macleods's ANDA Products, or any other drug product that is covered by or whose use is covered by the '708 patent, prior to the expiration of the '708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the '708 patent;

(e) A judgment that the '921 patent has been infringed under 35 U.S.C. § 271(e)(2) by Macleods's submission to the FDA of Macleods's '338 ANDA;

(f) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Macleods's '338 ANDA Product, or any other drug product that infringes or the use of which infringes the '921 patent, be not earlier than the latest of the expiration date of the '921 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(g) A preliminary and permanent injunction enjoining Macleods, and all persons acting in concert with Macleods, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Macleods's '338 ANDA Product, or any other drug product covered by or whose use is covered by the '921 patent, prior to the expiration of the '921 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(h) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Macleods's '338 ANDA Product, or any other drug product that is covered by or whose use is covered by the '921 patent, prior to the expiration of the '921 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the '921 patent;

(i) A declaration that this is an exceptional case and an award of attorney's fees pursuant to 35 U.S.C. § 285;

(j) Costs and expenses in this action; and

(k) Such further and other relief as this Court may deem just and proper.

Dated: February 13, 2020

Respectfully submitted,

/s/ Daniel M. Silver

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